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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/842,466

04/26/2001

Hiroyasu Kokubo

35576/233803

8005

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7590

04/04/2008

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

04/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/842,466	Applicant(s) KOKUBO ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-9, 11, 13-20 and 31-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9, 11, 13-20 and 31-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Response to Non-Final Office Action and Applicant's Arguments/Remarks, all filed 01/15/08 is acknowledged.

Claims 6-9, 11, 13-20 and 31-47 are pending in this action. No claim amendments have been filed herein. Claims 6-9, 11, 13-20 and 31-47 remain rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6-9, 11, 13-20 and 31-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berta (U.S. Pat. No. 4,820,524) in view of Hogan *et al.* (U.S. Pat. No. 6,406,738).

Berta ('524) teaches a solid, multi-colored medicament preparation having a multi-colored gelatinous coating, wherein the coating layer provides two or more different colors (see reference col. 4, lines 5-42). The medicament may be in the form of a caplet and contains a layer of gelatin as a single coating on the caplet core (col. 4, lines 43-56).

Berta also teaches a method for coating the solid cores, such as caplets, to produce simulated, capsule-like medicaments. Berta teaches that one objective of the invention is to provide a simulated, capsule-like medicament having a gelatinous coating capable of being

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provided in two or more colors. Another objective is to provide a heavy layer of gelatin as a *single* coating to cover imperfections inherent on the caplet core (col. 4, lines 12-56). During the drying process, the caplet may be rotated to assist in uniformly distributing gelatin during drying (col. 5, lines 46-65). Suitable coatings to be used are gelatinous materials, such as methyl cellulose, calcium alginate and gelatin. Additional ingredients disclosed include plasticizers, preservatives, coloring agents and opacifying agents (col. 8, lines 20-47).

Berta teaches a solid, multi-colored medicament wherein colorings can be added to the coatings to produce opaque or transparent colors, such as red, white, pink, green, reddish brown, blue, yellow and black, for example. To form white medicaments or an opaque colored coating, titanium dioxide is often added to the gelatin (col. 9, lines 1-7). Berta teaches that first and second ends of the caplet can be coated with gelatinous coatings of different colors to provide a distinctive appearance for specialty products (col. 9, lines 3-5); (col. 10, lines 29-62). Berta teaches that the solid, multi-colored medicament preparation additionally comprises various coating patterns (see Figs. 8 a-d and col. 5, lines 28-29). Berta does not explicitly teach a logo, letters or a bar code on the medicament. However, the inclusion of logos, bar codes or letters, as instantly claimed does not make the invention patentable since variations in designs or patterns in solid medicament forms is commonly and routinely practiced in the pharmaceutical art.

Berta teaches a solid preparation comprising a gelatinous coating that provides two or more colors wherein the medicament is smooth, shiny, multi-colored and has various coating patterns. These medicaments are pleasing to the eye, are easier to swallow than prior medicaments and offer a distinctive appearance, as similarly desired by the applicant.

Berta does not teach ‘exposing a first part of the coating layer to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parts of the coating layer having different coloration’. However, this limitation does not impart a patentable distinction over the reference teachings of Berta. A product is being claimed in which the solid preparation comprises more than one distinct coloring agent. It is the position of the Examiner that the prior art expressly teaches a multi-colored, tablet formulation consisting of a first and second different coloring agents, wherein the tablet is provided with a single, multi-colored continuous coating layer. The instant claims are product claims and it is the patentability of the product that must be established, *per se*. Applicants have not demonstrated any unexpected or surprising results that accrue from the multi-colored, continuous film coating layer as claimed. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

In this instance, the process of preparing the solid preparation does not afford patentable weight to the claims since Berta explicitly recognizes and teaches a solid medicament comprising a multi-colored, capsule-like coating, which is effective and aesthetically pleasing. The capsule-like medicaments have smooth, shiny, multi-colored gelatinous coatings thereon that are pleasing to the eye, easier to swallow and provide greater tamper resistance than conventional capsules.

In any event, **Hogan et al. ('738)** are relied upon for the teaching of a powder coating composition for electrostatic coating of pharmaceutical substrates. Hogan teaches electrostatic coating of cores of pharmaceutical tablets with a powder coating material, whereby treatment of the powder to form a film coating preferably involves a heating step, using infra red radiation as well as other forms of electromagnetic radiation (see column 1, lines 1-19); (col. 4, lines 32-35). Alternatively, the powder material may include a polymer which is cured during the treatment, for example by irradiation with energy in the gamma, ultraviolet or radio frequency bands, to form a cross-linked polymer film. The change in the powder material during treatment may be from a solid to liquid and then, on cooling, to a continuous solid film (col. 4, lines 35-44). The powder material includes a first component which forms a good continuous coat over the surface of the substrate (col. 7, line 61 – col. 8, line 16). Preferably the powder coating material further includes one or more colorants, for example, metal oxides or lakes (col. 9, lines 57-61). A different colored coating may be formed on each of the opposite faces of the tablet (col. 12, lines 30-44).

Hogan teaches fusing of the powder to provide for a uniform coating. The energy is provided by focused radiation (col. 16, lines 16-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the powder coating material methods of Hogan, which comprise the step of employing radiation, within the multi-colored tablet of Berta. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Hogan teaches that such a process would provide for a powder material having a good continuous coat over the surface of the substrate. The expected result would be an enhanced, multi-colored continuous

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coating layer having different colors along the body of the tablet for a pleasing colorful appearance for the consumer.

Response to Arguments

Applicant's arguments filed 01/15/08 have been fully considered but they are not persuasive.

▪ **35 U.S.C. 103(a) Rejection:**

Applicant argued, "Both Berta and Hogan describe tablets/tablets having two separate coatings that are separately applied to the solid preparation. The references fail to disclose or suggest a process that can be used to prepare a solid composition having a multicolored continuous film coating layer. The combination of references also fails to disclose the step of selectively irradiating the continuous coating to produce a coating having two distinct colors."

Applicant's arguments have been considered, but were not found to be persuasive. The Berta reference teaches that it is an objective of their invention to provide a layer of gelatin as a single coating to cover imperfections on the caplet core. See for instance, column 4, lines 43-56. Berta teaches a solid, multi-colored medicament preparation having a multi-colored gelatinous coating, wherein the coating layer provides two or more different colors (see col. 4, lines 5-42). The medicament being in the form of a caplet contains a layer of gelatin as a single coating on the caplet core. The secondary reference of Hogan was relied upon for the teaching of the treatment of a powder film coating whereby heating, using infrared radiation is applied. The reference further teaches that other forms of electromagnetic radiation or conduction or induction

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may be used. See for instance, col. 4, lines 32-35. Furthermore, Hogan teaches a continuous solid film (col. 4, lines 35-44).

Applicant argued, "One of ordinary skill in the art would not be motivated to irradiate the tablet of Berta because to do so would serve no purpose. The irradiation step in Hogan is necessary in order to melt and fuse the particles together in order to form a coating. Such a step is unnecessary in the process of Berta because the coating of Berta is provided as a liquid and as such there is no reason to apply irradiation to fuse the coating together as in Hogan."

This argument was not rendered persuasive. The issue here is whether the art teaches or suggests the advantages of employing irradiation in solid dosage formulations, which clearly it does. The secondary reference of Hogan demonstrates the use of irradiation methods provided in solid dosage formulations, such as tablets, whereby the reference further teaches cross-linking to yield different colors of the film coating layer. The reference teaches application of a coating provided over the entire surface of the tablet core (col. 12, lines 30-44); (col. 8, lines 14-16).

Applicant argued, "Neither Berta nor Hogan includes any teachings that their respective coatings would change color upon being irradiation. There is no basis for suggesting that the irradiation step of Hogan would result in changing the color of the coatings of either Berta or Hogan. The Office Action is using Applicants' own teachings in making this rejection. This is impermissible use of hindsight."

Applicant's arguments have been considered, but were not deemed persuasive. Hogan, as stated above, provides a method of treating a powder to form a film coating using radiation as a suitable means of treatment. Hogan states that the powder material may also include a polymer, which is cured during the treatment, for example by irradiation with energy in the

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gamma, ultra violet or radio frequency bands, to form a cross-linked polymer film. The argument that Applicant employs radiation for a different purpose than that of the prior art does not render a patentable distinction. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed.Cir. 2006).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant argued, "It cannot be predicted how irradiation would affect the structure of the coatings of Berta. The irradiating step of Hogan in the process of Berta would result in the tablet being unsatisfactory for its intended purpose."

The Examiner respectfully disagrees. Whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made. Ex parte Erlich, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986). Moreover, The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the

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prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this instance, Applicant has not sufficiently demonstrated as to how the irradiation methods supplied by Hogan would be detrimental to the capsule formulation of Berta.

Lastly, Applicant argued, "With respect to dependent claims 18-20 and 44-47, there is absolutely no teaching in either Berta or Hogan on how their respective teachings can be modified to produce a coating having a pattern, logo, bar code or letters."

This argument was not persuasive. The inclusion of patterns, logos and bar codes, as stated in the Office Action, is routine practice in the art of pharmaceutical tablets. While the combination references do not explicitly state the use of logos, patterns, or bar codes, the inclusion of such would provide for an aesthetically pleasing appearance as well as for easier identification of tablets, as is well known to one of ordinary skill in the art.

For these reasons, the rejections of record have been maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

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